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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,114	11/14/2005	F. C. Thomas Allnutt	026086.037.21 US	9387
24239 7590 08/07/2008 MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709				
EXAMINER				
BOESEN, AGNIESZKA				
ART UNIT		PAPER NUMBER		
16-48				
MAIL DATE		DELIVERY MODE		
08/07/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/519,114

**Applicant(s)**

ALLNUTT ET AL.

**Examiner**

Agnieszka Boesen

**Art Unit**

1648

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-48 is/are pending in the application.
- 4a) Of the above claim(s) 41-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-40 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### DETAILED ACTION

The Amendment filed May 5, 2008 in response to the Office Action of February 4, 2008 is acknowledged and has been entered. Claims 27, 31, 33, 34, 40 and 48 have been amended. Claims 27-40 and 48 are under examination in this Office Action.

#### *Claim Objections*

Objection to claims 33 and 40 under 37 CFR 1.75 (c) as being in improper form **is withdrawn** in view of Applicant's amendment.

#### *Claim Rejections - 35 USC § 112*

Rejection of claims 31, 34-40 and 48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment.

Rejection of claim 31 because of the lack of antecedent basis for the recitation of “complex” **is withdrawn** in view of Applicant's amendment.

Rejection of claim 48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** in view of Applicant's amendment.

#### *Claim Rejections - 35 USC § 102*

Rejection of claims 27, 28, 30-37, 38, 40 and 48 under 35 U.S.C. 102(b) as being anticipated by Chapman et al.(US. Patent 6,232,099 B1) **is withdrawn** in view of Applicant's amendment.

*However a new rejection is made below in view of newly found prior art*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 27, 28 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Balloul et al. (US Patent 7,354,591 B2).**

Claims are drawn to a method of producing a recombinant virus-like particle that targets specific tissue in a target animal, the method comprising providing a viral genome, isolating viral coat protein, inserting at least one first exogenous sequence encoding a protein or peptide of interest into the coat protein sequences, cloning the viral coat protein sequences and transforming a host organism. Claims are drawn to a recombinant virus like particle.

Balloul discloses an IMV poxviral recombinant virus like particle comprising an exogenous ligand that targets tissue antigens and a second exogenous protein of interest inserted in the coat protein of the virus like particle; and methods of producing a recombinant virus like particle expressing antibodies and other exogenous protein ligands recognizing and targeting specific tissues in an animal, the methods comprising providing a viral genome, isolating viral coat protein, inserting an exogenous sequence encoding a protein or peptide of interest, and inserting a second exogenous sequence into the coat protein sequences, cloning the viral coat protein sequences and transforming an E.coli host cell (see claims 1-14, Example 5, column 4, lines 30-67, column 5 and column 7, lines 30-67).

This by this disclosure Balloul anticipates the present claims.

***Claim Rejections - 35 USC § 103***

Rejection of claims 29 and 39 under 35 U.S.C. 103(a) as being unpatentable over Chapman et al.(US. Patent 6,232,099 B1) as applied to claims 27 and 34 and further in view of Harris et al. (International Immunology, 1997, Vol. 9, p. 273-280) **is withdrawn** in view of Applicant's amendment.

*However a new rejection is made below in view of newly found prior art*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 29, 34-40 and 48 are rejected under 35 U.S.C. 103(a) as being anticipated by Balloul et al. (US Patent 7,354,591 B2) in view of Harris et al. (International Immunology, 1997, Vol. 9, p. 273-280 of record on 2/4/2008).**

Balloul teaches therapeutic compositions comprising a recombinant virus like particle comprising an exogenous ligand that targets tissue antigens and a second exogenous protein of interest. Balloul does not teach the exogenous protein peptide being an allergen.

Harris teaches virus like particles expressing peptide epitopes of the major house dust mite allergen Der p1 (see the entire document).

It would have been obvious to provide a viral like particle expressing a protein or peptide that is an allergen. One would have been motivated to express Harris's major house dust mite allergen Der p1 in the viral coat protein of Balloul's virus like particle, because Balloul teaches

that antigenic epitopes of interest can be expressed in his VLPs (see column 5, lines 35-45), and because Harris teaches that VLPs serve as a strong antigen presentation system known to induce strong cell mediated immune responses and because Harris was able to in vivo prime the Th1 cells with the house dust mite antigens by administering house dust mite antigen expressing VLPs in mice (see Figures 1-4 and Discussion). Harris' allergenic protein and Balloul's tissue targeting ligand such as an antibody are two non-identical exogenous proteins.

One would have had a reasonable expectation of success to provide VLPs expressing allergenic epitope peptides because the recombinant virus technology used for making such recombinant VLPs has been well established in the art as evidenced by Balloul and Harris.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Thus **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen, Ph.D./  
Examiner, Art Unit 1648

/Stacy B Chen/  
Primary Examiner, Art Unit 1648